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Subject:

NEWS NCEA CAN USE

October 24, 2016

Competing Claims Over Glyphosate's Risks Pose Challenge For EPA SAP

By Dave Reynolds, Inside EPA Published October 21, 2016

Read the original article at: http://insideepa.com/daily-news/competing-claims-over-glyphosates-risks-pose-challenge-epa-sap

Pesticide industry officials and environmentalists are waging competing claims over the public health risks from the world's most commonly-used herbicide glyphosate in comments to a delayed EPA Science Advisory Panel (SAP), highlighting the challenge the panel faces in its pending work to assess evidence on the substance's risks.

"The overwhelming consensus of regulatory agencies and scientific organizations such as [EPA], Health Canada, the European Commission, and the World Health Organization is that glyphosate used according to label directions poses no unreasonable risk to humans, wildlife, or the environment," the National Cotton Council (NCC) says in written comments posted recently to EPA's docket for the pending review.

But environmental groups, including Food and Water Watch (FWW), Beyond Pesticides and the Pesticide Action Network, in <u>separate comments</u>, fault EPA's finding that glyphosate is unlikely to cause cancer as based on insufficient analysis that excluded consideration of studies of product formulations containing glyphosate.

"[W]e are concerned that the assessment relies too heavily on industry studies, downplays positive findings, and fails to consider the toxicity of glyphosate formulations," FWW says.

The SAP was originally slated to meet Oct. 18-21, with EPA in its <u>charge questions</u> to the panel saying it wants input on whether it should consider additional studies of glyphosate's cancer potential, on the strengths and uncertainties of its weight of evidence analysis of animal carcinogenicity studies, and on its interpretation of the reproducibility of certain studies, as well as on its evaluation of multiple lines of evidence.

However, <u>EPA announced Oct. 14</u> that it is delaying the panel until sometime later this year, citing recent changes in the availability of experts in assessing human exposures.

"Given the importance of epidemiology in the review of glyphosate's carcinogenic potential, the Agency believes that additional expertise in epidemiology will benefit the panel and allow for a more robust review of the data," EPA said in a statement. "As a result, the SAP meeting on glyphosate is being postponed to later in 2016."

EPA in June planned the SAP review to assess the agency's analysis of glyphosate's cancer risk. In announcing the review, the agency noted that recent reviews by other regulatory bodies have drawn conflicting conclusions. The SAP review will inform EPA's ongoing registration review of glyphosate as required by the Federal Insecticide, Fungicide, and Rodenticide Act.

As part of the planned review, EPA took comment through Oct. 17 on a Sept. 16 "Glyphosate Issue Paper: Evaluation of Carcinogenic Potential."

In the paper, EPA found that available evidence suggests glyphosate is not likely to pose a risk of human cancers at relevant doses, spurring industry calls for the agency to speed its ongoing registration review of the substance.

Environmentalists' Concerns

In the comments recently posted to EPA's public docket for the SAP review, pesticide producers and growers argue that EPA's issue paper finding that glyphosate is not likely to cause cancer is backed by overwhelming scientific evidence, and that glyphosate is vital to modern agriculture.

Environmentalists have long sought stricter EPA oversight of glyphosate, arguing heavy use of the substance, particularly since the advent of genetically-modified crops designed to withstand glyphosate in the 1990s, poses significant ecological and human health risks.

Those calls picked up in March 2015 when the World Health Organization's (WHO) International Agency for Research on Cancer (IARC) found glyphosate probably causes cancer, a conclusion that conflicted with other risk findings, even from within the WHO.

Industry and some House Republicans have faulted the IARC finding and argued that numerous other studies have yielded results consistent with EPA's recent finding that glyphosate is not likely to cause cancer at relevant doses. In the comments submitted in advance of the review, environmental groups fault EPA's issue paper, arguing the agency's review relied on industry studies, downplayed positive findings and failed to consider real-world exposures, which occur through formulated products rather than through the ingredient in isolation.

"Nearly half of the animal carcinogenicity studies found statistically-significant rates of tumor growth," FWW says. "Yet for many of the studies, EPA compares the results to unrelated control groups from other studies in order to reduce their statistical significance."

Beyond Pesticides defends IARC's March 2015 finding that glyphosate is probably carcinogenic, arguing IARC follows a "a well-defined and reputable cancer classification scheme" that considers human and animal data. The group notes that IARC assessed glyphosate and its formulated products, such as the commonly-used Roundup, while EPA's review did not.

Both FWW and Beyond Pesticides call for EPA to weigh risks of products containing glyphosate, rather than the substance alone. "Since glyphosate formulations contain numerous other ingredients, EPA must investigate the totality of these formulations and their carcinogenic potential as these chemical mixtures have the most relevance to human (and environmental) health," Beyond Pesticides says. "We urge EPA to be diligent in examining all the available evidence regarding the carcinogenic potential of glyphosate and its formulations."

Industry's Comments

But the pesticide industry and NCC back EPA's recent analysis as consistent with overwhelming evidence that glyphosate is safe when used properly, and that EPA's finding is accurate, while the IARC review is an outlier.

"Overall, Dow AgroSciences supports and is in agreement with the EPA's evaluation and interpretation of the available data, and we believe the Agency conducted a robust, science-based assessment in a highly transparent manner in reaching a determination of glyphosate as 'not likely to be carcinogenic to humans,'" <u>Dow says in its comments</u>. In <u>separate comments</u>, the Monsanto Company argues that the safety of glyphosate-based herbicides is backed by one of the most extensive human health and environmental effects databases ever compiled for a pesticide product.

"Comprehensive toxicological and environmental fate studies conducted over the last 40 years have time and again demonstrated the strong safety profile of this widely used herbicide," Monsanto says.

Meanwhile, the pesticide producers' group CropLife America (CLA) faults EPA's selection of a scientist for the review, saying he has publicly criticized industry-sponsored science as fundamentally flawed. <u>CLA, in comments</u>, is also opposing EPA's inclusion in the issue paper of plans for future consideration of product formulations, arguing that is beyond the scope of the SAP review.

In <u>an Oct. 12 letter to EPA</u>, CLA lobbies for the removal of one scientist from the SAP review and raises concerns about the involvement of another panelist.

CLA argues that ethical rules should preclude Peter Infante, a consultant based in Falls Church, VA, from participating in the SAP. CLA argues Infante's past statements suggest he will "reflexively discount" industry-sponsored studies. CLA also urges EPA to confirm that a second panelist, Kenneth Portier, of the American Cancer Society, may participate without pushing already-formed conclusions. CLA say Portier has urged manufacturers to come up with alternatives to glyphosate, which he considers a man-made carcinogen. The group also notes that his brother Christopher is a "vehement anti-glyphosate activist."

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